

Update Instructions

SP014/04/S

Title: Fixation of control console

Reason for update: ☒ SafetyUrgency: ☐ Immediate ☒ Within two (2) weeksUpdate materials required? ☒ Yes ☐ NoMaterials free of charge? ☐ Yes ☒ NoReturn of parts? ☐ Yes ☒ No

Estimated completion time: two (2) hours Number of CSE's: one (1)

Customer application training? ☐ Yes ☒ No**Systems/Products affected/System identifying IVK**

Name	Material No.	Serial No.
MAMMOMAT Novation DR	06646900	1002 - 1006,1008 - 1009 1011 - 1016,1018 - 1022

Remark: n.a.

Components affected/to be modified/IVK

Name	Material No.	Serial No.	Component status affected
Radiation protection and console support	06438894	n.a.	n.a.

Remark: n.a.

Chg. Ref. No.: TDSP-CR-03/04 0012
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Dept.: CS PS 24

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Document Revision Level

This document corresponds to the version/revision level effective at the time of system delivery. Revisions to hardcopy documentation are not automatically distributed.

Please contact your local Siemens office to order current revision levels.

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Systems/Products Affected

Following MAMMOMAT Novation DR Digital Mammography systems, System identifying IVK No: 066 46 900 are affected:

The range of serial numbers: 1002 - 1006, 1008 - 1009, 1011 - 1016 and 1018 - 1022.

Reason for the Update

The analysis of the incoming Installation Reports has shown that at some sites the Radiation shield and console carrier wasn't properly fixed to the floor.

It was observed that neither the corresponding wording within the former Revision (01) of the Planning Guide, nor the analogical wording in the Revision 04 of the Installation Instruction - Radiation shield - Print number SPB7-230.031.07.04.02 can be considered as completely clear. In order to ensure that the installation of this component (06438894) gets carried out properly, i.e. in accordance with the IEC 60601-2-32, not only the said documents were revised and actualised, but this safety-related Update Instruction is being issued, requiring:

1. an immediate crosscheck of fixation of the floor plate of the console carrier,
2. the rectification of fixation according to the revision 02 of the Planning Guide without delay wherever necessary, and
3. the reporting of this issue through due process.

Prerequisites

(Materials für Update)

Suitable dowels / anchor bolts according to data and to the description/ instruction in the actually applicable and valid Planning Guide (at the time when this instruction is being issued it is the Document Print number: SPB7-250.891.01.02.02 - Page 3-2. The dowels have to be procured on site. Application of sanitary silicone - as sealant around the floor plate - is recommended.

Special Tools / Documents

Suitable dowels / anchor bolts - see in Section Prerequisites (Materials for update).

Sanitary silicone,

Hammer drill,

Planning Guide, Print No: SPB7-250.891.01.02...

Ordering Information

No update kit is intended to be supplied with this instruction. Proceed according to information in Section Prerequisites (Materials for update) above.

Contents of the Update Kit

n.a. (see remark in Section Ordering Information above).

Return of Parts

n.a.

Work Steps

General information

There are two sales items with two sales material numbers for the "Radiation shield and control console carrier":

>> 044 94 345,

incorporating the MatNo: 6431774 - Lead glass with lead equivalent of 0.1 mm, and

>> 044 94 352,

incorporating the MatNo: 6551356 - Lead glass with lead equivalent of 0.3 mm.

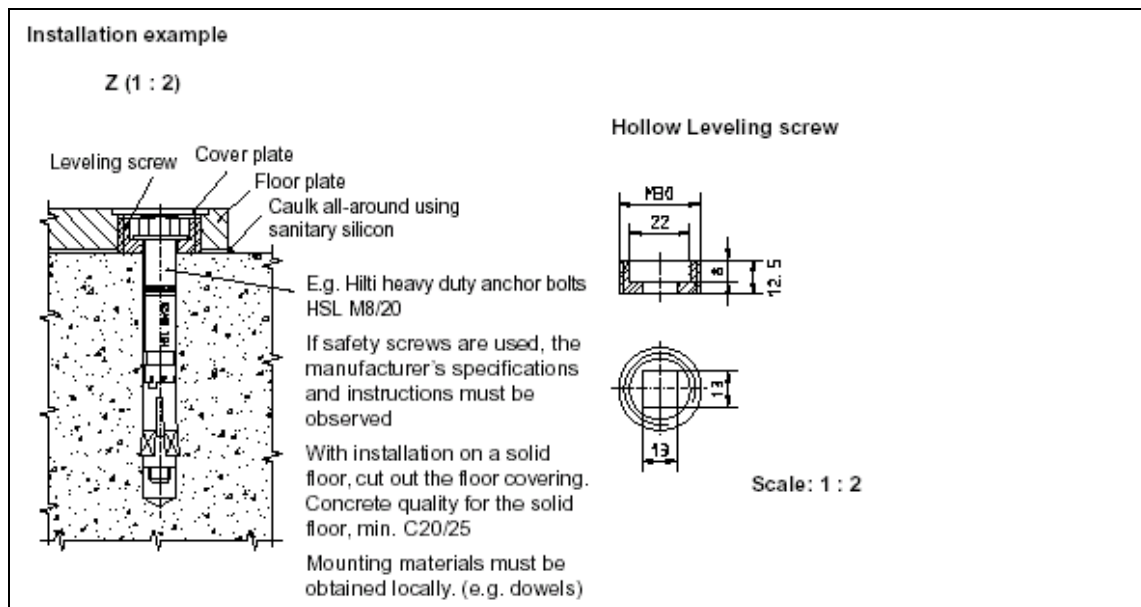
Both sales items incorporate also the material number 064 38 894, i.e. the "Console carrier kit" itself. The console carrier kit (to be assembled at site) consists of different parts, important for this UI are:

the material number 063 43 508 - Levelling screw, hollow, and

the material number 061 40 391 - Cover plate.

Two (2) of each should have been delivered to the site.

- Check whether the Radiation shield and console carrier has been installed in accordance with the corresponding description on the Page 3 - 2 of the Planning Guide.



- If yes, report this fact in manner usual for reporting about the Update Instructions, stating that the UI SP014/04/S has been complied with, (see under Final Work Steps).
- If not, proceed with correct fastening of the Radiation shield and console carrier. Level the carrier horizontally and vertically by means of the hollow levelling screws in the mounting plate and by means of the levelling bolt under the other side of the Radiation shield lead glass, apply the two dowels / anchors and tighten them. Cover the two openings by cover plates.
- Apply suitable sealant, e.g. sanitary silicone, around the mounting plate.

- Report the performance in the manner customary for reporting on the Update Instructions, stating that the UI SP014/04/S has been complied with, (see under Final Work Steps).

Final Check

- When the fixation work on the carrier / support is finished, perform a test exposure. Through this you can check that the work just performed on the console carrier didn't cause any possible damage to the Novation DR system.

Customer Information

Inform the Customer about the fixation of the console carrier.

Final Work Steps

- Update the system documentation. - not applicable.
- This update doesn't include an IVK.
- Updates that have already been completed prior to publication of this UI must also be reported.
- The Update is reported as follows: usually by the authorized personnel using an on-line application on the Intranet, or - for some regional units - in writing directly to Department CS PS 1 in the Headquarters in Erlangen.

Changes to Previous Version

n.a. - first Version.

Completion Protocol

The update instruction with the number **SP014/04/S** has been completed.

Material number: ...6646900.....

Serial number:

Customer: Functional Location:.....

Customer No.:

Name (CSE): Telephone:

Country: Location:

Date: Signature:

Remark:

.....

NOTE

After completing the update, make a copy of this page, fill it out and file it in the corresponding System Binder/User Handbook.
